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10/509,294	09/23/2004	Robert Schill	ETF0004US	3727

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EXAMINER

GWARTNEY, ELIZABETH A

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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08/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/509,294	Applicant(s) SCHILL ET AL.	
	Examiner Elizabeth Gwartney	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The Amendment filed 05/12/2009 has been entered. Claims 1-10 and 21 are pending.
2. The previous 112 2nd Paragraph rejections have been withdrawn in light of applicant's amendments made 05/12/2009.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1-9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hultin et al. (US 6,005,073) in view of Rogols (US 5,436,024).

Regarding claim 1, Hultin et al. disclose a process for the manufacture of intermediate food products in a form of hydrated concentrates of myofibrillar proteins from fish flesh (Abstract, C7/L44-49), said process comprising the following steps:

- an initial pulp of minced fish flesh is prepared from fish fillets (*see* deheaded and gutted fish fillets -C8/L54, *see* mince -Figure 4, C9/L2-4);

- said initial pulp is washed with water (C9/L5-9, Figure 4);

- said washed pulp is refined in the wet state by removing a fraction of impurities (*see* centrifuge removing oil, membrane, bone and skin - Figure 4;

- the pulp is drained to produce a densified pulp (*see* centrifuge/filter- Figure 4);

- cryoprotectants are added to the densified pulp to form a final pulp suitable for freezing (*see* cryoprotectants – Figure 4);

- and said final pulp is frozen (*see* freeze – Figure 4).

Hultin et al. do not disclose that the refined pulp is mixed until it is in a form of a homogenous emulsion, that the final pulp is packaged in a form of blocks, or that the initial pulp is washed to obtain a washed pulp containing a residual fraction of lipids and sarcoplasmic proteins comprised between 0.1% and 3% of the weight of the pulp.

Regarding packaging in a form of blocks, Rogols teaches that it is well known in the art to form surimi (i.e. processed fish mince) into blocks prior to freezing (C1/L35-38). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the processed fish mince of Hultin et al. into blocks prior to freezing because this

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procedure is commonly used for surimi processing and use of a known process step in a known environment to accomplish entirely expected results.

Regarding mixing the refined pulp to form a homogenous emulsion, while Hultin et al. disclose a process to manufacture intermediate food products in a form of hydrated concentrates of myofibrillar proteins (i.e. surimi) wherein fish pulp is homogenized with wash water (Figure 4) to form an emulsion, the reference does not explicitly disclose homogenizing refined pulp. Given homogenization of fish pulp containing protein and lipid forms an emulsion, since refined fish pulp contains both protein and lipid, it would be inherent that refined fish pulp forms a stable emulsion. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have homogenized the refined fish pulp of Hultin et al. rather than the unrefined fish pulp.

Hultin et al. fail to disclose that the initial pulp is washed to obtain a washed pulp containing a residual fraction of lipids and sarcoplasmic proteins comprised between 0.1 and 3% of the weight of the pulp. As processing efficiency and oxidative stability are variables that can be modified, among others, by adjusting the residual fraction of lipids and sarcoplasmic proteins in the washed pulp, the precise residual fraction of lipids and sarcoplasmic proteins would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the residual fraction of lipids and sarcoplasmic proteins in the washed pulp cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the residual fraction of lipids and sarcoplasmic proteins in the washed pulp of Hultin et al. to obtain the desired balance between processing efficiency and oxidative stability

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(*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 2, modified Hultin et al. disclose all of the claim limitations as set forth above and that the pulping operation is coupled with addition of water (see wash water – Figures 1 and 4).

Regarding claim 3, modified Hultin et al. disclose all of the claim limitations as set forth above and that about 1 to 9 or more volumes of water is added to the pulp (C9/L5-7).

Regarding claims 4 and 21, modified Hultin et al. disclose all of the claim limitations as set forth above. Given that Hultin disclose the removal of membrane, bone and skin from the minced and washed fish by centrifugation, it is clear that the pulping operation is a function of a density gradient in the fish fillets.

Regarding claim 5, modified Hultin et al. disclose all of the claim limitations as set forth above. Further, Hultin et al. disclose that the washing operation is composed of the following steps:

- water is added to the initial pulp and the whole is mixed to form a water-pulp mixture (C9/L5-7);

- the water-pulp mixture is centrifuged and the resulting water is removed (C9/L10-12);

- and the centrifuged pulp is washed continuously with water (Figure 2, C9/L8-9).

Regarding claim 6, modified Hultin et al. disclose all of the claim limitations as set forth above, however, the reference does not disclose that in the centrifugation step, a volume of water removed is between 80 and 95% of a volume of water initially used. As the recovery of

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sarcoplasmic proteins is a variable that can be modified, among others, by adjusting the volume of water removed in the centrifugation step, the precise volume removed would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed volume of water removed cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the volume of water removed in the centrifugation step in the surimi process of Hultin et al. to obtain the desired recovery of sarcoplasmic proteins (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 7, modified Hultin et al. disclose all of the claim limitations as set forth above. While Hultin et al. disclose mixing is carried out until a homogenized pulp is in a form of an emulsion, the reference fails to disclose that the emulsion has a stability of more than 10 minutes. As oxidative stability is a variable that can be modified, among others, by adjusting the stability of the fish pulp emulsion, the emulsion stability would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed emulsion cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the stability of the fish pulp emulsion of Hultin et al. to obtain the desired level of oxidative stability (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed

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in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claims 8-9, modified Hultin et al. disclose all of the claim limitations as set forth above and that the mixing step is followed by a deodorization of the emulsified pulp in which the latter is evacuated (*see* micronize under vacuum removing low molecular weight compounds responsible for off or rancid odors - C12/L42-45) and where the operation for draining the emulsified pulp is carried out by centrifugal decantation (Figure 4).

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hultin et al. (US 6,005,073) in view of Rogols (US 5,436,024) as applied to claim 1 above, and further in view of Shah et al. (WO 01/62888).

Regarding claim 10, modified Hultin et al. disclose all of the claim limitations as set forth above. While Hultin et al. disclose the addition of cryoprotectants, the reference does not explicitly disclose that the final pulp is subjected to a cold extrusion operation during the addition of cryoprotectants. Shah et al. teaches that it is well known in surimi processing to add cryoprotectants and extrude the final pulp prior to freezing (p.3/L3-5). Further, it is well known in the art that high temperatures will damage protein functionality. Therefore, it would have been obvious at the time the invention was made to have subjected the final pulp of Hultin et al. to a cold extrusion operation while adding cryoprotectants because doing so would amount to nothing more than use of a known surimi freezing process of its intended use in a known environment to accomplish entirely expected results. Further, doing so would protect the functionality of the refined protein.

Response to Arguments

8. Applicant's arguments filed 05/12/2009 have been fully considered but they are not persuasive.

Applicants explain that Applicant can rebut a presumption of obviousness if the prior art teaches away from the claimed invention or there are new and unexpected results relative to the prior art.

Applicants submit that claim 1 recites "washing said initial pulp to obtain a washed pulp containing a residual fraction of lipids and sarcoplasmic proteins comprised between 0.1 and 3% of the weight of the pulp. Applicants argue, given Hultin teaches the separation of insoluble impurities including lipids, fats and oils by centrifugation and that said impurities degrade and render the product unacceptable, Hultin "very clearly teaches away from maintaining a residual fraction of lipids in such a food product."

While Hultin et al. disclose impurities, including membrane lipids, "render the product unacceptable", Hultin et al. clearly discloses a finished product with an amount of lipid, i.e. with 0.12-0.14% (C15/Table 2), that overlaps with the amount presently claimed. Therefore, given Hultin et al. disclose a fish protein product comprising some lipid, i.e. 0.12-0.14% (C15/Table 2), identical to the quantity presently claimed, it can not be said that Hultin et al. teaches away from "maintaining a residual fraction of lipids in such a food product."

Further, applicants allege unexpected results based on evidence present in specification ([0151]-[0152] of published application). Applicants submit that the "[a]pplicant's disclosure teaches that maintenance of lipids and sarcoplasmic protein in the finished product considerably raises a yield of the overall process. [T]hus a raising of the lipid content of the product by

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merely 1% allows for a 12% raise in yield.” Applicants argue that this improvement is unexpected. In fact, applicants argue, any positive result achieved by the presence of lipid would be considered unexpected relative to the "unacceptable" teaching of Hultin.

Given Hultin et al. disclose a fish protein product comprising some lipid, i.e. 0.12-0.14% (C15/Table 2), identical to the quantity presently claimed, it is clear that the product would intrinsically display the same yield increases relative to a product without lipid.

In the alternative, the question as to whether unexpected advantage has been demonstrated is a factual question. *In re Johnson*, 747 F.2d 1456, 1460, 223 USPQ 1260, 1263 (Fed. Cir. 1984). Thus, it is incumbent upon applicant to supply the factual basis to rebut the prima facie case of obviousness established by examiner. See, e.g., *In re Klosak*, 455 F.2d 1077, 1080, 173 USPQ 14, 16 (CCPA 1972). Applicants, however, have not shown that comparison samples in said disclosure fairly represent the closest prior art. In this case, Hultin et al. discloses typical protein recovery two times that demonstrated by applicant, i.e. 42% (C15/Table 1). Therefore, it is unclear if protein recovery, i.e. .yield, is a result of lipid content or some other processing condition.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday; 7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./

Examiner, Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794